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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,563	07/01/2002	Jan Otto Solem	JM-050 CON	8701
30452	7590	02/08/2005	EXAMINER	
EDWARDS LIFESCIENCES CORPORATION ONE EDWARDS WAY IRVINE, CA 92614			JACKSON, SUZETTE JAMIE	
			ART UNIT	PAPER NUMBER
			3738	
DATE MAILED: 02/08/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/019,563	SOLEM ET AL.	
	Examiner Suzette J Gherbi	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 24 January 2005.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 11-13, 15-19 and 21-65 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 11-13, 15-19 and 21-65 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1.) Certified copies of the priority documents have been received.  
 2.) Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3.) Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/31/01</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

1. Applicant RCE dated 1/24/05 has been received in application serial number 10/019,563. The amendment to the specification dated 1/24/05 and 5/26/04 has also been received.

### *Specification*

2. The amendment filed 5/26/04 and 1/18/05 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: On page 3 "...the wires 26, 27 are "secured" to the stents and the ends of the wires have been severed and removed. Applicant is required to cancel the new matter in the reply to this Office Action and re-instate the original disclosure with the exception of corrected spelling/grammatical errors.

### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 11-13, 15-19, 21, 28 (teeth), 29 (mesh), 31 (clip), 32-41 (coupling mechanism) , (180 angle of degrees); 40-41, 45-47 (sheath), 48 (clip), 51-62 (secured), 63-64 (anchor, anchoring and secured, securing) rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In particular applicant has claimed subject matter that is not mention and or supported by the specification. Applicant may think that these terms/changes are minor however they change the scope of the invention. For example, applicant claims "secured" but the specification state "connected". When something is connected it is not necessarily securely connected. Applicant's specification states on page 8 that the **stents** (not anchors) may be positioned in the coronary sinus as illustrated by conventional means such that their positions are "fixed". They are "connected" by wires....". Another example as to how the minor amendments change the scope is that the stent and now claimed as anchors. A stent supports a blood vessel or organ as a scaffold wherein an anchor can take on a variety of forms and does not have to support the blood vessel. There is also no mention of clips, teeth and other materials as claimed. These changes therefore change the scope of the originally filed application. Applicant must claim the invention as disclosed.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 23-25, 30, 31, 48 rejected under 35 U.S.C. 102(b) as being anticipated by Mehra 5,170,802. Mehra discloses the invention as claimed comprising: A device for effecting the condition of a mitral valve annulus of a heart with a resilient member (14) having a cross sectional dimension capable of being received within the coronary sinus (12) of the heart and having a longitudinal dimension having an arched configuration (the arched configuration is achieved in figure1) for partially encircling the mitral valve and exerting an inward pressure on the mitral valve when within the coronary sinus adjacent the mitral valve *for constricting the mitral valve annulus* (the constricting achieved because of the current being delivered to the heart and stress placed on the annulus as a whole.).

***Response to Amendment/Remarks***

7. Applicant has amended the claims and addressed the priority concerns from the prior office action dated 8/16/04. The priority claim is acknowledged. The application

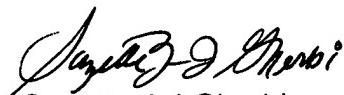
appears to have a number of claims with limitations not supported by the specification (as addressed above in paragraph 3). Applicant is encouraged to read the specification and each claim to make sure the all terms are supported without changing the scope of the invention.

***Conclusion***

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J. Jackson whose work schedule is Monday-Friday 9-6:30 off every other Friday and whose telephone number is 571-272-4751.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



Suzette J-J Gherbi  
04 February 2005